Supreme Court, U.S.
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No. 95-1644

In The

Supreme Court of the United States

October Term, 1995

COLLAGEN CORPORATION,

Petitioner,

v.

CHARLOTTE KENNEDY AND ROBERT KENNEDY,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 360c et seq., preempt state law claims to recover damages for injuries caused by a medical device?

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STATEMENT

The question of whether the Medical Device Amendments of 1976 ("MDA") preempt state damages actions is presently under review by this Court in *Medtronic v. Lohr*, No. 95-754 and No. 95-886, argued April 23, 1996.

The MDA preemption questions raised in *Medtronic* are analogous to those presented here by Petitioner in *Kennedy*. The two cases differ factually in that the Class III device in *Medtronic* was cleared for marketing under 21 U.S.C. Sec. 360(k), commonly known as the "510(k) process" for "substantially equivalent" devices, while Petitioner Collagen Corporation's Class III device (Zyderm) was cleared for marketing under the premarket application process of 21 U.S.C. Sec. 360c, commonly known as "PMA approval."

As Section 360k(a) of the MDA does not preempt state-law claims for personal injury, the manner in which a Class III device reaches the market would be immaterial for preemption purposes. *Medtronic* should answer many questions regarding federal preemption of state laws under the MDA as to Class III medical devices. But to the extent that *Medtronic* leaves open any question as to the scope of the MDA preemption, certiorari should nonetheless be denied in this case because the lower court correctly determined that the Kennedy's claims are not preempted by the MDA.

DISCUSSION

1. As with *Medtronic*'s pacemaker, the design of Collagen's Zyderm originated with the company, not with the FDA. The FDA allowed Petitioner Collagen to market a device with that design, but it did not *require* that particular design. "Pre-market approval" is merely what it says: marketing approval, not marketing requirements. The FDA has not established any design requirements for Collagen's Zyderm device.

Rather, the relevant inquiry is the federal requirements applicable to the device. Like the device in *Medtronic*, the Zyderm device at issue in this case is not subject to any counterpart requirements that preempt personal injury claims.

Similarly, the FDA approves a PMA product's labeling, but does not itself draft the labeling. The FDA also allows the manufacturer to add warning and contraindications to its product's labeling without prior approval from the agency. *See infra* at page 5. Once the PMA-approved device is marketed, it is subject to the same good manufacturing practice regulations and the same labeling regulations as any other Class III device.

2. *Kennedy*, in acknowledging and applying the applicable MDA provisions and regulations as an integrated whole, correctly holds that the MDA and its related regulations do not preempt personal injury claims such as those brought by Respondents.

Kennedy recognizes that while Congress may have provided for preemption of state law under Section 360k(a), it is not an unlimited preemption, particularly in

light of FDA regulations promulgated under the MDA. These regulations state that in order for there to be preemption of a state law claim, the FDA must have first established *specific* counterpart regulations applicable to a *particular* device. 21 C.F.R. Sec. 808.1(d). As *Kennedy* held, the Class III PMA-approval process is not a "specific regulation" applicable to a "particular device," and there are no specific regulations promulgated for the design, manufacture or labeling of Zyderm. Therefore, as to this medical device, there is no preemption of Respondents' causes of action.

Moreover, as *Kennedy* correctly recognizes, Section 360k(a) does not preempt state or local requirements of *general applicability* under Section 808.1(d) (i.e., requirements applicable to products in addition to medical devices), and state common law is law of general applicability not relating solely to or regulating any medical device, but other products as well.

Because Congress has charged the FDA with implementing and interpreting the MDA, the agency's position on MDA preemption is entitled to substantial deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984). The FDA's position is "dispositive unless its interpretation is inconsistent with clearly expressed congressional intent." *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985) (deferring to the FDA's position narrowly construing preemption of state and local regulations of blood donation centers, despite comprehensive federal regulation). Thus, *Kennedy*, properly follows 21 C.F.R. Sec. 808.1(d) and gives deference to the FDA under *Chevron*.

Kennedy was properly decided, for both analytical and public policy reasons. "Reasonable" assurance of safety and efficacy through the PMA-approval process is merely the beginning, not the end, of medical device considerations. Section 360k(a) was not intended to supplant a manufacturer's responsibility and liability to users of its medical devices.

The petition should be denied.

CORRECTION OF MISSTATEMENTS IN THE PETITION

As required under Rule 15.1, Rules of the Supreme Court, Respondents note the following misstatements appearing in the Petition for Writ of Certiorari, which bear, or may bear, on the issues presented by this case.

1. Throughout its Petition, Collagen Corporation cites to the federal regulations governing pre-market applications ("PMA") for Class III medical devices, 21 C.F.R. Sec. 814, et seq. As Collagen's medical device "Zyderm" is a Class III "PMA approved" device, the Petition creates the impression that Zyderm underwent the rigors of PMA approval under 21 C.F.R. Sec. 814, et seq. In fact, however, Zyderm was approved in 1981, but the applicable federal PMA regulations were not effective until 1986. As a result, the Class III PMA device involved in this action did *not* undergo the PMA approval process set out in 21 C.F.R. Sec. 814.20, et seq.

2. At Page 6 of its Petition, Collagen quotes certain written "conditions of approval" issued in the FDA's approval of Zyderm, which conditions (inter alia) require

FDA approval of any labeling changes that may affect the safety or effectiveness of the device. The Petition creates the illusion that Collagen was unable to add the autoimmune disease warnings that form the basis of Respondents' "failure to warn" claim below. Collagen's Petition omits the following subsequent portion of the subject "conditions of approval" which actually *authorizes* Collagen to add safety warnings without waiting for FDA approval:

> Changes in labeling . . . which enhance safety of the device or safety in the use of the device may be [made] prior to the receipt of a written FDA approval . . .
>
> Specific examples of changes permitted are:
>
> (1) Addition of warnings, contraindications or side effects.

As a result, Collagen Corporation was authorized to add autoimmune warnings to the device package labeling without waiting for FDA approval.

4. At Page 6 Collagen asserts that "Since 1981, Collagen has marketed Zyderm as a prescription-only medical device strictly in accordance with these conditions and other requirements imposed by the FDA." This assertion is incorrect. In 1991, Collagen's Zyderm devices were seized and partially destroyed by the FDA and the U.S. Department of Justice as misbranded, mislabeled and/or adulterated medical devices, due to Collagen's violations of package labeling/PMA regulations for the devices. Moreover, Petitioner Collagen Corporation actively promoted Zyderm for unapproved uses, in violation of FDA regulations. *See Is the FDA Protecting Consumers From*

Dangerous Off-label Uses of Medical Drugs and Devices?, House Rep. No. 102-1064, 102d Cong., 2d Sess. at 8-9, 24-28 (GPO 1992).

5. At Pages 6 and 7, Collagen states that in 1991, after 10 years of clinical experience, the FDA reaffirmed Zyderm's finding of safety and effectiveness. This statement is misleading. The FDA "re-review" was of Collagen's original PMA application materials based upon 1981 standards, *not* an update with a decade of additional information under 1991 standards. This "re-review" did nothing more than find that the original PMA had been properly processed accordingly to 1981 Section 360c standards.

CONCLUSION

This petition should be denied.

Respectfully submitted,

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